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09/484,704	01/18/00	HENRICKSON K	650053.91126

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EXAMINER	
SIEW,J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/484,704	Applicant(s) HENRICKSON ET AL.	
	Examiner J ffrey Si w	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cov r sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *6,12,20 & 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,13-19,21,22 and 24-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Election/Restrictions

1. Applicant's election of claims 1-5,7-11,13-19,21,22 & 24- 33 in Paper No. 6 is acknowledged. Claims 6,12,20 & 23 withdrawn from further consideration as being drawn to a nonelected nucleotide sequences. Election was made in Paper No. 6.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,3,7,8,10,13-18,21 & 24-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No.

5,744,299 in view of Orle et al (US5,508,168 April 16, 1996) and Cerutti et al (US5,187,060 Feb. 16, 1993).

Claims 1,2,3,7,8,10,13-18,21 & 24-27 are drawn to exposing cDNA to SEQ ID NOs 1-9 which amplify human parainfluenza virus 1 and exposing cDNA to at least one additional primer pair which are designed to amplify influenza virus.

Claims 1-19 of U.S. Patent No. 5,744,299 are drawn to exposing cDNA to SEQ ID Nos 1-9 which amplify human parainfluenza virus 1 and additionally binding to marker, binding to solid support, detecting by probe specific for HN or the biological sample is respiratory secretion and the kit containing primers SEQ ID NO. 1-9.

Claims 1-19 are not drawn due exposing with additional primer pair to amplify influenza virus.

Orle et al teach detection of multiple viruses that causes disease using sequence specific primers for simultaneous amplification (see abstract).

Cerutti et al teach detection of influenza A virus by amplification of conserved region of HA gene using amplimers (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply both the Orle et al's method of simultaneous detection and Cerutti et al's primers of influenza A virus to the claims 1-19 of US6,744,299 in order to detect the respiratory viruses HPIV-1 and influenza simultaneously. Orle teach that multiple pathogen detection in a single PCR assay increases the amount of diagnostic information at a single test. It would have been prima facie obvious to apply additionally Cerutti et al's primer pairs for influenza to the claims of U.S. Patent No.

5,744,299 so maximum detection of the infectious agents would be detected within the time frame of one assay.

4. Claims 4,5,9,11 & 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,744,299 in view of Orle et al (US5,508,168 April 16, 1996) and Cerutti et al (US5,187,060 Feb. 16, 1993) in further view of Randolph et al (US5,932,222 August 3, 1999) and Briedis et al (J. of Vir. Vol. 42 No. 1 pp. 186-193 1982).

Claims 4,5,9,11 & 19 are drawn to exposing cDNA to SEQ ID NOs 1-9 which amplify human parainfluenza virus 1 and exposing cDNA to detecting the claimed combination of additional viruses.

Claims 1-19 of U.S. Patent No. 5,744,299, Cerutti et al and Orle et al are described previously.

Claims 1-19 of U.S. Patent No. 5,744,299 are not drawn to the claimed additional viruses.

Randolph et al teach PCR of RSV genome sequence from genomic viral RNA of both subgroup A and B (see abstract and col. 17 line 29-col. 18 line 31).

Briedis teach Influenza B virus genome sequence and mRNAs of NS proteins (see abstract).

One of ordinary skill in the art would have been motivated to apply the viral sequences of Randolph et al and Breides to the multiplex and simultaneous PCR detection of Orle et al and claims of U.S. Patent No 5,744,299 in order to additionally detect the claimed combination of

viruses in a single assay. It would have been prima facie obvious to apply the cited prior art sequences of RSV A & B and Influenza B to design primers for the multiple PCR detection method of Orle et al so that rapid diagnostic detection of the infectious agents would be performed in a shorter time of a single assay and at lower cost instead of performing each amplification separately.

5. Claim 28& 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,015,664. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 28 & 29 are drawn to exposing nucleic acid to primer pairs specific for HPIV-1,2 & 3, RSV A& B and Influenza virus A & B. Claim 1 is drawn to exposing nucleic acid to primer pairs specific for HPIV-1,2 & 3, RSV A& B and Influenza virus A & B wherein the 5' and 3' primers are in unequal concentration. Claim 1 represents a species type method would render obvious the genus method claims 28 & 29.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-11, 13-19,21,22, 24-27 & 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-5, 7-11,13-19,21,22 & 24-27 are confusing because the language "selected from" is not proper Markush language. It is unclear as to the what is being selected. Clarification is requested.

B) Claim 9 recites the language " the results " and depends on claim 5 . However, proper antecedent basis is lacking in the parent claim. If the claim were amended to " the amplification products", the rejection would be overcome.

C) Claims 4,5,10 & 11 are confusing. Claims must be recited in a positive, active fashion and clearly refer back to the preamble of the claim. See ex parte Erlich, 3 USPQ2, p. 1011 (Bd. Pat. A.P. In. 1986). It is suggested that all claims be amended to set forth active steps e.g. ...additionally comprising the step of ...

D) Claim 22 is confusing because it cannot be determined as to which set of probes are being selected. Particularly, it cannot be determined as to whether different strains of RSV are being referred to.

E) Claims 30-33are confusing because they appear as Jepson claims but it is unclear as to what limitations are associated with the preamble (see MPEP 2129 & 608.01(m)).

F) Claims 32 & 33 are confusing because it is unclear as to what stage during the denaturation is occur during PCR amplification e.g. before amplification cycles or during the cycling.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu (EP0418960 A2 March 27, 1991).

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Mullis (US4,683,202 July 28, 1987).

Mullis teach heat denaturation for two times for 5 minutes for amplifying DNA sequence (see col. 16 line 1).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orle et al (US5,508,168 April 16, 1996) in view of Karron et al (J. Clinical Micro vol. 32 no. 2 pp. 484-88 1994), Precious et al (J. of Gen. Vir. Vol. 71 pp. 1163-1168 1990), Henrickson et al (J. of Inf

Diseases vol. 166 pp. 995-1005 1992), Randolph et al (US5,932,222 August 3, 1999), Cerruti et al (US5,187,060 Feb. 16, 1993) and Briedis et al (J. of Vir. Vol. 42 No. 1 pp. 186-193 1982) .

Orle et al teach detection of multiple viruses that causes disease using sequence specific primers for simultaneous PCR amplification (see abstract).

Orle et al do not teach the claimed viruses.

Karron teach PCR rapid detection of HPIV-3 of HN gene using RT-PCR (see whole doc. esp. abstract).

Precious et al teach sequence analysis of HN gene of HPIV-2 (see whole doc.).

Henrickson et al teach HN sequence variation of HPIV-1(see whole doc.).

Randolph et al teach PCR of RSV genome sequence from genomic viral RNA of both subgroup A and B (see abstract and col. 17 line 29-col. 18 line 31).

Cerutti et al teach detection of Influenza A virus by amplification of conserved region of HA gene using amplimers (see whole doc. esp. abstract).

Breides teach Influenza B virus genome sequence and mRNAs of NS proteins (see abstract).

One of ordinary skill in the art would have been motivated to apply the viral sequences of the cited prior art to the multiplex and simultaneous PCR detection of Orle et al in order to rapidly detect the multiple respiratory infectious agents at one time. It was well known and commonly practiced in the art to design primers from known sequences. The cited prior art taught the conserved sequences of genes of various respiratory viruses. It would have been prima facie obvious to apply the sequences of HPIV1-3, RSV A & B and Influenza A & B to design primers for the multiple PCR detection method of Orle et al so that rapid diagnostic detection of

the infectious agents would be performed in a shorter time of a single assay and at lower cost instead of performing each amplification separately.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orle et al (US5,508,168 April 16, 1996) in view of Karron et al (Jo. Clinical Micro vol. 32 no. 2 pp. 484-88 1994), Precious et al (J. of Gen. Vir. Vol. 71 pp. 1163-1168 1990), Henrickson et al (J. of Inf Diseases vol. 166 pp. 995-1005 1992), Randolph et al (US5,932,222 August 3, 1999), Cerruti et al (US5,187,060 Feb. 16, 1993), and Briedis et al (J. of Vir. Vol. 42 No. 1 pp. 186-193 1982) in further view of Orth et al (5,712,092 Jan. 27, 1998).

The teachings Orle et al are described previously.

Orle et al do not explicitly teach a kit.

Orth et al teach a generic kit containing probes for viral detection (see col. 17 lines 11 - 13).

One of ordinary skill in the art would have been motivated to apply Orth et al's teachings of kit containing viral oligonucleotides to PCR method of Orle et al so that the practitioner to would have the assay reagents readily available to perform the detection efficiently. Kits were well known and commonly practiced in the art at the time of the invention. It would have been prima facie obvious to combine all the reagents i.e. different primers specific for HPIV-1,2 &3, RSV A& B and Influenza A& B into a single kit as taught by Orth et al in order for the practitioner to carry out the simultaneous and multiple detection method quickly and efficiently.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu (EP0418960 A2 March 27, 1991) in further view of Mullis (US4,683,202 July 28, 1987).

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

Wu et al do not teach denaturation of 5 minutes.

Mullis teach heat denaturation for 5 minutes (see col. 16 line 1)

One of ordinary skill in the art would have been motivated to apply Mullis' teaching of heat denaturation times to Wu et al's PCR amplification in order to achieve successful separation of DNA strands. It would have been prima facie obvious to apply Mullis teachings to Wu et al's PCR in order to optimize the PCR conditions to successfully amplify product.

SUMMARY

13. Claim 22 is free of the prior art but rejected under 112 second paragraph.

There is no prior art that teach a kit containing the pair of primers of the SEQ ID Nos. 1-9 and one pair of primers to RSV A and B and influenza A and B and additionally comprising oligonucleotide probes specific for HN gene of HPIV 1,2 or 3, influenza A virus M gene, and influenza virus B NS gene.

CONCLUSION

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. The examiner can best be reached on Monday through Thursday from 6:30 a.m. to 4 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Fax (703) 308-4556 or (703) 308-4242.

Jeffrey Siew

November 29, 2000